Serial Number: 10/647,838

Filing Date: August 25, 2003

Title: HARDWARE/SOFTWARE LOCK FOR SECURE LINKAGE BETWEEN ALGORITHMIC DECISION PROCESS AND CRITICAL

SYSTEM FUNCTION EXECUTION

IN THE CLAIMS

- 1. (Original) An implantable medical device to perform a therapy, the device comprising:
 - a therapy circuit for use to provide the therapy;
 - a sensing circuit to sense a need and send a request for the therapy; and
- a controller coupled to the sensing circuit and the therapy circuit, the controller to receive a request for the therapy, and upon receiving the request, the controller to perform a process, including:

setting a token for use to unlock the therapy;

- running an algorithm to insure the legitimacy of providing the therapy, and executing an unlock code to insure an appropriate outcome for the algorithm; and
- unlocking the therapy when the token is set and when the outcome for the algorithm is appropriate.
- The device of claim 1, wherein the therapy includes electrical therapy to a heart. 2. (Original)
- 3. (Original) The device of claim 2, wherein the electrical therapy includes pacing therapy.
- The device of claim 2, wherein the electrical therapy includes high energy 4. (Original) electrical therapy.

5. (Original) The device of claim 1, wherein:

running an algorithm to insure the legitimacy of providing the therapy, and executing an unlock code to insure an appropriate outcome for the algorithm:

> writing a first message to a first memory address before running the algorithm; running the algorithm to insure the appropriateness of providing the therapy; and writing a second message to a second memory address after running the algorithm; and

unlocking the therapy when the token is set and when the outcome for the algorithm is appropriate includes unlocking the critical therapy when the first and second messages indicate the outcome for the algorithm is appropriate.

- 6. (Original) The device of claim 1, wherein setting a token includes writing to one or more memory locations.
- The device of claim 1, wherein running an algorithm includes running an error 7. (Original) checking routine.
- 8. (Original) The device of claim 1, wherein the appropriate outcome for the algorithm includes an indication that the critical therapy is appropriate and an indication that the algorithm was run in its entirety.
- 9. (Original) An implantable medical device in communication with electrical activity of a heart, the device comprising:
- at least one electrode adapted to sense electrical signals related to the electrical activity and adapted to deliver electrical therapy to the heart;
- a sensing circuit coupled to the at least one electrode to provide electronic signals representative of the electrical activity;
 - a therapy circuit coupled to the at least one electrode to deliver the electrical therapy; and
- a controller coupled to the sensing circuit and therapy circuit, the controller to perform a process, including:

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receiving a request for the therapy based on the electronic signals representative of the electrical activity of the heart;

setting a token for use to unlock the therapy;

verifying the legitimacy of the request for the therapy process, including running an algorithm to insure the appropriateness of providing the therapy, and executing an unlock code to insure a satisfactory outcome for the algorithm; and

unlocking the therapy when the outcome of the algorithm is satisfactory and the token is set to indicate the therapy is appropriate.

10. (Original) The device of claim 9, wherein:

running an algorithm to insure the appropriateness of providing the critical therapy, and executing an unlock code to insure a satisfactory outcome for the algorithm includes:

writing a first message to a first memory address before running the algorithm; running the algorithm to insure the appropriateness of providing the critical therapy; and

writing a second message to a second memory address after running the algorithm; and

unlocking the critical therapy when the token is set and when the outcome for the algorithm is satisfactory includes unlocking the critical therapy when the first and second messages indicate the outcome for the algorithm is satisfactory.

11. (Original) The device of claim 10, wherein:

the device further includes memory;

writing a first message includes writing a first value to a first memory location; and writing a second message includes writing a second value to a second memory location.

12. (Original) The device of claim 11, wherein the first and second memory locations include hardware registers.

13. (Original) The device of claim 9, wherein setting a token includes writing to one or more memory locations.

- 14. (Original) The device of claim 9, wherein the electrical therapy includes pacing therapy.
- 15. (Original) The device of claim 9, wherein the electrical therapy includes high energy electrical therapy.
- 16. (Original) The device of claim 9, wherein running an algorithm includes running an error checking routine.
- 17. (Original) A method, comprising:

receiving a request for a therapy;

setting a token for use to unlock the therapy;

to verify the legitimacy of the request for the therapy process, running an algorithm to ensure the appropriateness of providing the therapy, and executing an unlock code to insure that running the algorithm results in a satisfactory outcome; and

unlocking the therapy when the token is set and running the algorithm results in a satisfactory outcome.

- 18. (Original) The method of claim 17, wherein unlocking the therapy when the token is set and running the algorithm results in a satisfactory outcome includes unlocking the therapy when the token is set and running the algorithm results in an indication that the therapy is appropriate and an indication that the algorithm was run in its entirety.
- 19. (Original) The method of claim 17, wherein running an algorithm includes executing an error-checking routine.

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20. (Original) The method of claim 17, further comprising rejecting the request for therapy when the token and the first and second messages do not indicate that the therapy is appropriate and that the algorithm was run in its entirety.

21. (Original) The method of claim 17, wherein the therapy includes electrical therapy from an implantable medical device.

22. (Original) A method, comprising:

receiving a request for a therapy;

setting a token for use to unlock the therapy;

writing a first message prior to running the algorithm;

running the algorithm to ensure the appropriateness of providing the therapy

writing a second message to indicate an outcome resulting from running the algorithm;

and

unlocking the therapy when the token and the first and second messages indicate that the therapy is appropriate and that the algorithm was run in its entirety.

- 23. (Original) The method of claim 22, wherein unlocking the therapy when the token and the first and second messages indicate that the therapy is appropriate and that the algorithm was run in its entirety includes unlocking the therapy when the token and the first and second messages result in an indication that the therapy is appropriate and an indication that the algorithm was run in its entirety.
- 24. (Original) The method of claim 22, wherein running an algorithm includes executing an error-checking routine.
- 25. (Original) The method of claim 22, further comprising rejecting the request for therapy when the token and the first and second messages do not indicate that the therapy is appropriate and that the algorithm was run in its entirety.

RESPONSE UNDER 37 CFR § 1.111

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26. (Original) The method of claim 22, wherein the therapy includes electrical therapy from an implantable medical device.